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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

BLANCO, JAVIER G

ART UNIT PAPER NUMBER

3738

DATE MAILED: 10/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,848

Applicant(s)

ALBREKTSSON ET AL.

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 June 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Drawings

1. Applicants' incorporation of Figures 9-14 in the reply filed on June 22, 2004 is acknowledged. However, according to the drawings sheets submitted June 22, 2004, Figures 11-14 were not included with the Response/Amendment. There are 6 (six) drawings sheets. Three representing Figure 9, three representing Figure 10.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 38, 39, 52, and 53 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Serbousek (US 5,098,434).

As seen in Figures 1-5, Serbousek discloses a fixture (screw 20) having a relatively short frusto-conical proximal section (see section between head 22 and shoulder member 28), a proximal cylindrical section (shank 24) having a screw thread profile thereon (threaded member 26), and a distal end (see end of shank 24). The frusto-conical proximal section and the proximal cylindrical section each being dimensioned to as to bear against the cortex of the femur neck when the fixture is in an anchored position (see column 2, lines 45-55).

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4. Claims 38, 39, 55-61, 63, 67, and 73 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Rambert et al. (GB 2 033 755 A).

As seen in Figure 1, Rambert et al. disclose a femur fixture for a hip-joint prosthesis, comprising an intraosseous anchoring structure of a generally circular cross-section for screwing laterally into a complementary bore drilled laterally into the neck of a femur after resection of the femur head to an anchored position (see entire document), the intraosseous anchoring structure comprising a head section (cylindrical thread 4 + conical bearing 5), a collar section (plate 2) having a distal surface abutting said intraosseous anchoring structure (see Figure 1), a relatively short frusto-conical proximal section (threaded rod 7), a proximal cylindrical section (recall screw 15) having a screw thread profile, and a distal end (threaded head of 15) that projects through the lateral cortex of the femur when the intraosseous anchoring structure is in the anchored position (see Figure 1; see entire document).

Response to Arguments

Applicant's arguments filed June 22, 2004 have been fully considered but they are not persuasive.

a. Applicants argue that Rambert et al. '755 threaded rod 7 "is not "relatively short" in relation to the recall screw 15, and is not "relatively short" in relation to the intraosseous anchoring structure as a whole". Examiner respectfully disagrees. First, under M.P.E.P. 2113.03, the transitional term "comprising" is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997). Second, as seen in Rambert et al. '755 Figure 1, there is a "relatively short frusto-conical proximal section at the proximal end" (see first 1/3 of

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threaded rod 7). Third, “relatively” is a broad term. Applicants’ arguments are based on a point of reference (i.e., is not “relatively short” in relation to the recall screw 15; is not “relatively short” in relation to the intraosseous anchoring structure as a whole). Claim 38 does not disclose the “frusto-conical proximal section” as been “relatively short” in relation to other structure.

b. Applicants also argue that Rambert et al. ‘755 recall screw 15 “cannot be regarded as a proximal cylindrical section”. Examiner respectfully disagrees. As seen in Rambert et al. ‘755 Figure 1, the first 1/3 of recall screw 15 (inside threaded rod 7) could be interpreted as a proximal threaded cylindrical section.

c. The limitations on which the Applicants rely (i.e., “Rambert et al. do not address the problem with the lack of loading of the cortical bone”; “there is no resemblance between the functions of the threaded bore with the recall screw and the frusto-conical proximal section with the proximal section cylindrical section according to the present invention”) are not stated in the claims. It is the claims that define the claimed invention, and it is claims, not specifications that are anticipated or unpatentable. *Constant v. Advanced Micro-Devices Inc.* 7 USPQ2d 1064.

5. Claims 38, 52-54, and 67 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Vrespa (US 5,593,410 A).

As seen in Figure 8, Vrespa discloses a fixture having a relatively short frusto-conical proximal section (see top part of said fixture), a proximal cylindrical section (threaded shank 23), and a distal end (threaded shank 14). The frusto-conical proximal section and the proximal cylindrical section dimensioned to as to bear against the cortical bone of the bone.

Regarding the intended use (i.e., for a hip-joint prosthesis, for screwing laterally into a complementary bore drilled laterally into the neck of a femur), it is noted that the law of

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anticipation does not require that the reference “teach” what the subject patent teaches, but rather it is only necessary that the claims under attack “read on” something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Response to Arguments

Applicant's arguments filed June 22, 2004 have been fully considered but they are not persuasive.

a. Applicants argue that “the alleged frusto-conical proximal section and a portion of the threaded shank 23 are positioned outside of the bone in a counter-acting element 82 and they do not form part of an intraosseous anchoring structure”. Examiner respectfully disagrees. In the case a plate 82 is not needed, a countersink could be provided in order to have the frusto-conical proximal section embedded into the cortex and/or cortical portion of the bone.

b. The limitations on which the Applicants rely (i.e., “Vrespa does not address the problem with the lack of loading of the cortical bone”) are not stated in the claims. It is the claims that define the claimed invention, and it is claims, not specifications that are anticipated or unpatentable.

Constant v. Advanced Micro-Devices Inc. 7 USPQ2d 1064.

c. It is noted that the law of anticipation does not require that the reference “teach” what the subject patent teaches, but rather it is only necessary that the claims under attack “read on” something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983).

6. Claims 38, 52-54, and 56-67 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by *Hansson et al.* (US 5,588,838 A).

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As seen in Figures 1 and 3, Hansson et al. disclose a fixture having a relatively short frusto-conical proximal section (conically flaring portion 10), a proximal cylindrical section (cylinder body 1) having a screw thread profile, and a distal end. Said relatively short frusto-conical proximal section comprises circumferentially oriented micro-threads/micro-beads (character 9 or character 109).

Regarding the intended use (i.e., for a hip-joint prosthesis, for screwing laterally into a complementary bore drilled laterally into the neck of a femur), it is noted that the law of anticipation does not require that the reference “teach” what the subject patent teaches, but rather it is only necessary that the claims under attack “read on” something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Response to Arguments

Applicant's arguments filed June 22, 2004 have been fully considered but they are not persuasive. Applicants argue that, with regards to the size of the fixture, “there is a clear structural difference”. Examiner respectfully disagrees. The fixture of Hansson et al. ‘838 comprises the structural limitations as claimed in claims 38, 52-54, and 56-67. It is possible to use said fixture as a femur fixture for small mammals.

7. Claims 38, 40-54, 67, and 74 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Kaneko (US 5,863,167 A).

As seen in Figure 1, Kaneko discloses a fixture having a collar/head section (head 12), a relatively short frusto-conical proximal section (see section below the collar/head section), a

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proximal cylindrical section (parallel thread part 13) having a screw thread profile, a distal cylindrical section (smaller diameter parallel thread part 15) having a screw thread profile, a frusto-conical connecting section (taper thread part 14) interconnecting said proximal and distal cylindrical sections, and a tapered distal end (taper bit 16).

Regarding the intended use (i.e., for a hip-joint prosthesis, for screwing laterally into a complementary bore drilled laterally into the neck of a femur), it is noted that the law of anticipation does not require that the reference “teach” what the subject patent teaches, but rather it is only necessary that the claims under attack “read on” something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Response to Arguments

Applicant's arguments filed June 22, 2004 have been fully considered but they are not persuasive.

a. Applicants argue that the trumpet section 12 “is not a frusto-conical proximal section”.

Examiner respectfully disagrees. There is a “relatively short frusto-conical proximal section” between head 12 and parallel thread part 13 (see section below the collar/head section).

b. Regarding the intended use (i.e., for a hip-joint prosthesis, for screwing laterally into a complementary bore drilled laterally into the neck of a femur), it is noted that the law of anticipation does not require that the reference “teach” what the subject patent teaches, but rather it is only necessary that the claims under attack “read on” something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device

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is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 68-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rambert et al. (GB 2 033 755 A) in view of Sotereanos (US 6,284,002 B1).

Rambert et al. disclose the subject matter of claims 38, 39, 55-61, 63, 67, and 73 except for particularly disclosing the distal surface 21 of the collar section 20 as being inclined inwardly. However, Sotereanos discloses a femur fixture comprising a collar section 20 having a distal surface 32 inclined inwardly and provided with micro-beads 22/24 in order for the collar section to contact substantially all of the resected surface of the femur and to provide additional surface for bone ingrowth (see entire document). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teaching of providing a femur fixture with a collar section having a distal surface inclined inwardly and provided with micro-beads, as taught by Sotereanos, with the femur fixture of Rambert et al., in order for the collar section to contact substantially all of the resected surface of the femur and to provide additional surface for bone ingrowth.

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Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Huggler (US 4,129,903), Weber (US 4,224,699), Kleiner (US 4,976,740), Hasegawa et al. (US 5,310,343), Thramann (US 5,360,448), Grundei et al. (US 5,766,263), Storer et al. (US 6,626,948), Baroud et al. (DE 197 25 269), and Grundei et al. (JP 11-56883).

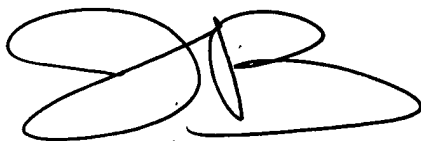
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 703-605-4259. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

October 12, 2004



David H. Willse
Primary Examiner